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D. FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	ATTORNEY DOCKET NO. CONFIRMATION NO.	
(	01/16/2002	Paul M. Stull	RADME-58551 7930		
7590	11/16/2005		EXAMINER		
FULWIDER PATTON			AHMED, A	AHMED, AAMER S	
	3		ARTINIT	PAPER NUMBER	
10TH FLOOR LOS ANGELES, CA 90045					
	7590 DER PATTO TER DRIVI	01/16/2002 7590 11/16/2005 PER PATTON TER DRIVE DOR	01/16/2002 Paul M. Stull 7590 11/16/2005 PER PATTON TER DRIVE DOR	01/16/2002 Paul M. Stull RADME-58551  7590 11/16/2005 EXAM DER PATTON AHMED, A TER DRIVE DOR ART UNIT	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)					
	10/051,870	STULL, PAUL M.					
Office Action Summary	Examiner	Art Unit					
	Aamer S. Ahmed	3763					
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence add	dress				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION  16(a). In no event, however, may a reply be tim  ill apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONEI	I.  lely filed  the mailing date of this cor  O (35 U.S.C. § 133).	,				
Status							
•	action is non-final.	secution as to the	marite is				
	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims		0.0.210.					
4)⊠ Claim(s) <u>1-10,12-21,23-64 and 67-74</u> is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>1-10,12-21,23-64 and 67-74</u> is/are rejected.							
7) Claim(s) is/are objected to.							
8) Claim(s) are subject to restriction and/or	election requirement.						
Application Papers							
9) The specification is objected to by the Examine	r.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau	(PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.							
Attachment(s)							
1) Notice of References Cited (PTO-892)	4) Interview Summary						
<ul> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)</li> <li>Paper No(s)/Mail Date 04/19/05, 05/24/04.</li> </ul>	Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other: <u>IDS 03/22/20</u>	rmal Patent Application (PTO-152)					

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#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-10, 12-14, 36-48, 64, 67-70, 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lasheras U.S. 6,726,708 in view of Ward et al U.S, 5,716,386. Lasheras discloses a method of manipulating the temperature of a patient comprising steps of positioning a balloon catheter in the stomach of the patient, exchanging heat between the balloon catheter and the stomach so as to controllably alter the temperature of a substantial portion of the patient's body, introducing a heat exchange fluid into the balloon catheter, wherein heat is exchanged between the balloon catheter and the stomach so as to controllably alter the temperature of at least a portion of the patient (entire reference). Lasheras fails to explicitly disclose expanding the balloon catheter to a size and shape that distends the stomach. Ward et al discloses a similar method in which a balloon catheter is expanded to a size and shape that distends the stomach (col. 11 line 27). It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of Lasheras by incorporating the stomach distending balloon of the type taught by Ward et al in order to secure the device in place.

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Claims 18-21 and 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lasheras U.S. 6,726,708 in view of Wittenberg et al U.S. 6,575,933. Lasheras discloses a method of manipulating the temperature of a patient comprising steps of positioning a balloon catheter in the stomach of the patient, exchanging heat between the balloon catheter and the stomach so as to controllably alter the temperature of a substantial portion of the patient's body, introducing a heat exchange fluid into the balloon catheter, wherein heat is exchanged between the balloon catheter and the stomach so as to controllably alter the temperature of at least a portion of the patient (entire reference). Lasheras fails to explicitly disclose maintaining the heat exchange fluid at a temperature below zero degrees centigrade. Wittenberg et al discloses a similar method including maintaining the heat exchange fluid at a temperature below zero degrees centigrade (col. 5 line 47). It would have been obvious to one having ordinary skill in the art at the time of invention to modify the method of Lasheras by incorporating the step of maintaining the heat exchange fluid at a temperature below zero degrees centigrade as disclosed by Wittenberg et al in order to cool the tissue.

Claims 15-17, 49-51 and 71-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lasheras and Ward et al in view of Dae (US 6,231,594). Lasheras and Ward et al disclose all of the claimed limitations as described above in reference to claims 1, 36 and 64, except administering an anti-shivering mechanism to the patient. Dae does disclose administering an anti-shivering mechanism to the patient. It would have been obvious to one of ordinary skill in the art to combine the teachings of Lasheras, Ward et al and Dae and administer an anti-shivering mechanism to the patient in order to prevent him/her from shivering.

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Claims 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lasheras and Wittenberg et al and further in view of Dae. Lasheras and Wittenberg et al disclose all of the claimed limitations as described above in reference to claims 1, 36 and 64, except administering an anti-shivering mechanism to the patient. Dae does disclose administering an anti-shivering mechanism to the patient. It would have been obvious to one of ordinary skill in the art to combine the teachings of Lasheras, Wittenberg et al and Dae and administer an anti-shivering mechanism to the patient in order to prevent him/her from shivering.

## Response to Arguments

Applicant's arguments filed April 19 2005 have been fully considered but they are not persuasive. Applicant argues that amended independent claims 36 and 64 overcome the Lasheras as the temperature probe as they recite that the temperature probe is introduced into the vasculature of the patient to obtain a core temperature and that Lasheras teaches away from this. However, Lasheras does teach that a monitor 128 may determine the core temperature as is known in the art with which core body temperature be monitored. Applicant's contention that inserting a temperature probe is counter to the Lasheras patent is not convincing since temperature probes introduced in the vasculature are known in the art.

Applicant's arguments with respect to claims 1 and 18 have been considered but are moot in view of the new ground(s) of rejection.

### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. Ahmed

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